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The author assesses the circumstances in which clinical trials might be considered invalidating public uses under the America Invents Act.

Clinical Trials as Potentially Invalidating Public Uses: Current Issues and Future Questions Under the Leahy-Smith America Invents Act

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Introduction

When is a clinical trial an invalidating public use of an invention? Courts have struggled with this question—one particularly important in the pharmaceutical, biotechnology, and medical device industries—for years.

Patent protection is one of the primary reasons investors are willing to risk money in developing new pharmaceuticals and medical devices. However, U.S. patent law prohibits an inventor from obtaining a patent on any invention that was in ''public use'' more than one year before the application leading to the patent was filed, unless the use was primarily experimental in nature.

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Clinical trials are required in order to determine whether a new product is safe and effective. They also necessarily involve testing on patients, and so inherently must involve the public, to some extent. And for good ethical reasons, patients participating in trials must be informed what drugs or devices are tested on them.

Clinical trials are clearly experimental in nature, not commercial, because they are subject to a very real risk of failure and provide no direct economic benefit to the companies sponsoring them. They are also usually tightly controlled and performed according to a detailed protocol, so that the general public has little or no practical access to the invention being tested.

The question as to whether a clinical trial is an invalidating public use will be further complicated by changes to the definition of prior art implemented by the Leahy-Smith America Invents Act of 2011, Pub. L. 112-29. Under current law, an inventor has a one-year grace period to file her patent application after there is a ''public use'' of the invention in the United States. This grace period applies to all public uses, even those by third parties, and current law completely disregards

public uses outside the U.S. for purposes of prior art. Under new Section 102(a)(1),[1] as set forth under the AIA, however, third party public uses will be prior art up until the earliest effective filing date, and any public use anywhere in the world will be considered potential prior art.

At the same time as the AIA broadens the universe of prior art geographically and temporally, it seems to limit the universe of prior art to those public uses that are ''available to the public.''[2]

As discussed below, the legislative history of this addition to the definition of prior art also suggests that this term is meant to be a limiting condition, and that some instances of invalidating public uses are no longer intended to be considered prior art, if they are not truly ''available to the public.'' If the AIA is read this way by courts, it will likely weigh against finding that any well-controlled clinical trial is an invalidating public use.

A careful reading of the Federal Circuit and district court cases that have squarely addressed this question offer a short list of key issues that have led courts to determine when a clinical trial is, or is not, an invalidating public use. A recent district court decision, *Dey Inc. v. Sepracor Inc.*,[3] now pending on appeal, serves to illustrate many of these issues in the context of a third party clinical trial (i.e., one conducted by someone other than the patentee).

What constitutes an invalidating public use will be much more important when the AIA's prior art definition is applied. These issues are further explored below.

Statutory and Supreme Court Background

Section 102(b) of the Patent Act, which defines prior art, states simply that: ''A person shall be entitled to a patent unless: . . . (b) the invention was . . . *in public use* or on sale in this country, more than one year prior to the date of the application for patent in the United States.''[4]

The last time the Supreme Court addressed the ''public use'' or ''on sale'' terms in this section was in 1998, in *Pfaff v. Wells Electronics Inc.*[5] *Pfaff* set a new standard for application of the ''on-sale'' bar in Section 102(b), holding that the on-sale bar should apply when, before the one-year-prior critical date, the invention was (i) the subject of a commercial offer for sale and (ii) ''ready for patenting.''

The ready for patenting prong may be satisfied by either (a) ''reduction to practice,'' or (b) the preparation of drawings and descriptions sufficient to enable practice of the invention. Under this rule, an invention may be the subject of an invalidating offer for sale even if it has not been actually reduced to practice.

In reaching this holding, *Pfaff* relied on prior Supreme Court jurisprudence regarding the experimental use doctrine, which applies to both the public use and on sale bars. Under the experimental use doctrine, an otherwise public use or sale of the invention will not be considered invalidating if the public use or sale was conducted primarily for the purpose of experimentation and perfection of the invention being tested.

Pfaff cited the 1877 decision in *Elizabeth v. Pavement Co.*[6] in support of its conclusion that so long as the invention is no longer the subject of any bona fide effort to bring the invention to perfection, the one-year bar should begin as soon as the invention is ready for patenting.[7]

Elizabeth held that the public use of a new type of roadway in the City of Boston was not a public use because the inventor came to visit it regularly to see how it was holding up.[8] *Pfaff* expressly confirmed that ''an inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention—even if such testing occurs in the public eye.''[9]

The court's discussion of the experimental use exception is particularly relevant in the public use context because the ''ready-for-patenting'' prong of the *Pfaff* test was later applied by the Federal Circuit to set a new standard for application of the public use bar, in *Invitrogen Corp. v. Biocrest Manufacturing Inc.*,[10] which is addressed later in this article.

The Federal Circuit's False Start

The Federal Circuit's first attempt to answer the question of when a clinical trial is an invalidating public use of an invention suggested that most clinical trials should be considered invalidating public uses. After that decision was attacked by amici curiae as inconsistent with precedent and incorrect as a matter of policy, it was vacated by the Federal Circuit, sitting en banc, removing it from the Federal Circuit's published precedent.

Subsequent Federal Circuit decisions have approached this question differently, and upheld district court decisions finding that a well-controlled clinical trial should not be considered an invalidating public use.

It is instructive, however, to examine the facts and reasoning of the district court and the Federal Circuit in connection with the circuit's first attempt, which reversed a district court's decision on summary judgment of no invalidity under the public use bar of Section 102(b).[11] Interestingly, the district court's reasoning was largely adopted by the Federal Circuit in later cases.

The trials at issue in this case were classic Phase III trials of paroxetine hydrochloride hemihydrate, or ''PHC hemihydrate,'' to determine its safety and efficacy for treating depression. The trials were not completed until after the application leading to the '723 patent at issue was filed.[12] Importantly, Claim 1 of the '723 patent, the only claim at issue, was directed to crystalline paroxetine hydrochloride hemihydrate. The other

[1] 35 U.S.C. § 102(a)(1).

[2] 35 U.S.C. § 102(a)(1) (as amended by the Leahy-Smith America Invents Act of 2011, Pub. L. No. 112-29, 125 Stat. 284 (2011)) (''A person shall be entitled to a patent unless . . . the claimed invention was . . . in public use, . . . *or otherwise available to the public* before the effective filing date of the claimed invention'') (emphasis added).

[3] 847 F. Supp. 2d 541 (S.D.N.Y. 2012).

[4] 35 U.S.C. § 102(b) (emphasis added).

[5] , 525 U.S. 55, 48 USPQ2d 1641 (1998).

[6] 97 U.S. 126.

[7] *Pfaff*, 525 U.S. at 64-65.

[8] 97 U.S. at 136-37.

[9] *Pfaff*, 525 U.S. at 64.

[10] 424 F.3d 1374, 76 USPQ2d 1741 (Fed. Cir. 2005) (70 PTCJ 663, 10/14/05)

[11] *SmithKline Beecham v. Apotex Inc.*, 286 F. Supp. 2d 925 (E.D.N.Y. 2001).

[12] *Id.* at 932.

  PTCJ ISSN 0148-7965

claims of the '723 patent were not asserted; they were directed to the treatment of depression with the compound of Claim 1.[13]

The district court decision in *SmithKline* held that the clinical trials were not an invalidating public use because they were experimental uses.[14] As a threshold matter, the court found that the fact that the trials were not controlled directly by the inventors did not disqualify them from being considered experimental uses. The trials were conducted by the assignee of the invention and could qualify because they played a role in refining the invention and demonstrating its efficacy. The court also found that the evidence that the trial participants complied with the written protocol supported the conclusion that the trials were experimental, even though they were not completely confidential.[15]

The district court decision in *SmithKline* was the first one to have an opportunity to interpret and apply *Pfaff* to the question of when the experimental use exception could apply, and concluded that the exception could apply until the invention was reduced to practice.[16] The court also found that the clinical trials at issue were conducted as part of determining whether the claimed invention worked for its intended purpose, the treatment of depression, and so were conducted before the invention was reduced to practice. The court rejected Apotex's argument that reduction to practice and proof that the invention would work for its intended purpose had been established before the critical date by other trials cited in the patent at issue.[17]

On appeal in 2004, the Federal Circuit reversed in a 2-1 decision, *SmithKline Beecham v. Apotex*.[18] Judge Randall R. Rader, writing for the majority with Judge William Curtis Bryson, held that *Pfaff*'s ''ready for patenting'' rule applies to trigger the public use bar: ''§ 102(b) erects a bar where, before the critical date, the invention was ready for patenting and was used by a person other than the inventor who is under no confidentiality obligation.''[19]

The majority found that the record showed that PHC hemihydrate was in public use because it was administered to the patients in the trials without confidentiality restrictions on the patients or on the physicians, who knew that PHC hemihydrate was being tested.[20]

The majority on appeal in *SmithKline* also found that, even assuming the trials were well-controlled (and so experimental in nature), they could not be considered experimental uses negating a public use because they did not test the *claimed invention* (the compound PHC hemihydrate).[21] The majority opinion noted that the claimed invention had been construed as a compound defined without reference to its efficacy, commercial use, or pharmaceutical viability. The court reasoned that because the antidepressant properties of PHC hemihydrate are not claimed features, clinical trials directed to its antidepressant properties cannot qualify as experimental uses that negate the statutory bar.[22]

The majority opinion went on to try and harmonize this decision with three earlier decisions finding the experimental use negation applied where the testing at issue did *not* focus on a claimed feature of the invention. These three cases are *Manville Sales v. Paramount Systems*,[23] *Seal-Flex v. Athletic Track and Court Construction*,[24] and *EZ Dock Inc. v. Shafer Systems Inc.*[25] Rader characterized these three cases as ones that ''permitted testing to negate the bar when the experimentation improves or verifies a feature inherent in the express claims of the invention.''[26]

In a concurring opinion, Judge Arthur J. Gajarsa agreed with the judgment of invalidity on other grounds, but expressly disagreed with the majority's conclusion that the clinical trials constituted an invalidating public use under Section 102(b).[27] Rather, Gajarsa agreed with district court that the trials were experimental and directed to determining whether the claimed invention was capable of performing its intended purpose in its intended environment. Gajarsa argued that the facts in the three earlier Federal Circuit cases discussed by the majority opinion could not be meaningfully distinguished from the facts in the *SmithKline* action, because those cases also involved experimental testing of inventions where the intended purpose of the invention was not expressly claimed.[28]

SmithKline Beecham petitioned for rehearing en banc on the court's invalidity determinations and several amicus briefs were filed. Several amici argued that the decision created significant uncertainty as to whether a well-run clinical trial will later be found to be a public use.[29]

These same amici noted that other, non-asserted claims of the patent at issue were specifically directed to the use of PHC hemihydrate as an antidepressant, showing the inventors' intent to use the claimed invention to treat depression, the only use disclosed in the patent in suit. They argued that a compound's utility is an intrinsic part of the claim.[30]

Other amici argued that the invention was really directed to solving problems other than treatment of depression, in particular problems relating to commercial scale manufacturing.[31] These amici argued that the decision would not have a chilling effect on pharmaceutical investment because other provisions of the patent law would incentivize pharmaceutical investment, such

[13] *Id.* at 928-29.
[14] *Id.* at 932-937.
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] 365 F.3d 1306, 70 USPQ2d 1737 (Fed. Cir. 2004) (67 PTCJ 611, 4/30/04).
[19] *Id.* at 1316-17.
[20] *Id.* at 1317.
[21] *Id.* at 1317-18.
[22] *Id.*
[23] 917 F.2d 544, 16 USPQ2d 1587 (Fed. Cir. 1990).
[24] 98 F.3d 1318, 40 USPQ2d 1450 (Fed. Cir. 1996).
[25] 276 F.3d 1347, 61 USPQ2d 1289 (Fed. Cir. 2002).
[26] *SmithKline Beecham*, 365 F.3d at 1318-20.
[27] *Id.* at 1324.
[28] *Id.* at 1324-25.
[29] *See, e.g.*, Brief of Amicus Curiae Intellectual Property Owners Association in Support of Petition for Rehearing En Banc, *SmithKline Beecham Inc. v. Apotex Inc.*, 403 F. 3d 1331 (Fed. Cir. June 14, 2004); Brief of Amicus Curiae Pharmaceutical Research and Manufacturers of America in Support of the Petition for Rehearing En Banc, *SmithKline Beecham Inc. v. Apotex Inc.*, 403 F. 3d 1331 (Fed. Cir. June 14, 2004).
[30] *Id.*
[31] *See, e.g.*, Brief of Amicus Curiae Generic Pharmaceutical Association in Opposition to Petition for Rehearing En Banc, *SmithKline Beecham Inc. v. Apotex Inc.*, 403 F. 3d 1331 (Fed. Cir. July 21, 2004).

as the five year regulatory exclusivity awarded to new chemical entities and provisions of the Hatch-Waxman law allowing the addition of up to five years of patent life to patents covering approved new drugs.[32]

The Federal Circuit granted rehearing en banc, vacated the panel opinions, and remanded to the same panel for reconsideration.[33] The panel simultaneously issued new opinions holding the patent claim at issue invalid on different grounds, namely, inherency.[34] Surprisingly, all discussion of the Section 102(b) ''public use'' issue was removed from the new panel and concurring opinions, leaving the application of public use law to clinical trials for another day.

The Federal Circuit Tries Again

Only two months after vacating its *SmithKline Beecham* opinions, the Federal Circuit tried again, this time tentatively swinging in the other direction.

In June 2005, it issued a nonprecedential affirmance of a trial court decision finding a patent not invalid. In *Janssen Pharmaceutical N.V. v. Eon Labs Manufacturing Inc.*,[35] the court affirmed with little discussion a trial court decision finding that a bioequivalency trial looking at fasted versus non-fasted blood levels was not a public use.[36]

The court did not rely on the experimental use exception. It affirmed the lower court's finding that the trial was not sufficiently accessible to the public to be a ''public use,'' even though there were no confidentiality agreements with patients or doctors regarding the tested composition.[37]

Janssen relied on the fact that the invention (a composition of beads and certain size cores) was not disclosed in the protocol or to doctors or patients. The court also noted that a strict protocol was followed and that any unused drugs should have been returned to Janssen. The court also noted that Janssen received no money (suggesting that the trial was not for a commercial purpose) and was very small, with only 28 people involved.[38]

Then, in October 2005, the Federal Circuit issued a decision written by Rader that reset the standard for considering public use invalidity. In *Invitrogen Corp. v. Biocrest Manufacturing L.P.*,[39] the court reversed a summary judgment of public use invalidity. The alleged public use (which was admittedly the claimed invention) was a process used internally by Invitrogen to make cells used in other Invitrogen research, but which were not sold commercially.[40]

The court applied the Supreme Court's *Pfaff* decision, directed to Section 102(b)'s related on-sale bar, to that section's public use bar, holding that the public use bar arises where the invention is in public use and ready for patenting before the critical date.[41] In doing so, the court noted that the experimental use exception may negate either the ready for patenting or the public use prong of the test, even though the experimental use negation was not at issue in *Invitrogen*.[42]

Interestingly, for purposes of interpreting the new AIA Section 102(a)(1) invalidity standard, *Invitrogen* stated that the proper test for the public use bar is whether the purported use was ''accessible to the public'' or commercially exploited.[43]With the inclusion of ''or otherwise available to the public'' in AIA Section 102(a)(1), arguments will be made that inaccessible commercial exploitation of inventions, particularly process inventions, will no longer qualify as prior art.

Invitrogen noted that to qualify as public, a use must occur without any ''limitation or restriction, or injunction of secrecy,'' citing *Egbert v. Lippman*[44] for this proposition.[45] In *Egbert*, the inventor of a new type of corset spring gave samples to a lady friend for her unrestricted use for a number of years before seeking a patent.[46] This is arguably an example of a public use that is not really available to the public, as it is a use that is made without any limitation or restriction that is not effectively available to the public in any practical way.

The *Invitrogen* court did confirm that express confidentiality restrictions are not required to keep a use from being considered an invalidating public use; a patentee may rely on circumstances creating an expectation of secrecy to show that a prior use was not sufficiently public to qualify as a public use.[46]

The Federal Circuit swung further toward a general understanding that a well-conducted clinical trial should not be considered a public use in 2006, in *Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals Inc.*[47] In a decision authored by Rader and joined by Gajarsa and Judge Alvin A. Schall, the court affirmed the trial court's holding that the patent claims at issue were not invalid under Section 102(b) for public use.[48]

The clinical trial at issue was a Phase I trial conducted entirely in a restricted Lilly facility under strict security measures, although patients were allowed visitors. The claimed inventions were both the compound olanzapine and a method of using this drug to treat schizophrenia.

Eli Lilly affirmed the lower court's finding that the trials were not public, and also affirmed the lower court's experimental use finding, stating that ''even a use that occurs in the open may not invoke a bar when undertaken to experiment on or with the claimed invention.''[49] In contrast, in the vacated *SmithKline Beecham* decision, the asserted claims were directed to the compound itself, and a Federal Circuit panel found that clinical trials to test the utility of the compound did not qualify for the experimental use exception because they

[32] *Id.*
[33] *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1328, 74 USPQ2d 1396 (Fed. Cir. 2005) (69 PTCJ 613, 4/15/05).
[34] *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 74 USPQ2d 1398 (Fed. Cir. 2005) (69 PTCJ 613, 4/15/05).
[35] 134 Fed. App'x 425 (Fed. Cir. 2005).
[36] *Id.* at 431.
[37] *Id.*
[38] *Id.*
[39] 424 F.3d 1374, 76 USPQ2d 1741 (Fed. Cir. 2005) (70 PTCJ 663, 10/14/05).
[40] *Id.* at 1379.
[41] *Id.* at 1379-80.
[42] *Id.*
[43] *Id.* at 1380.
[44] 104 U.S. 333 (1881).
[45] *Invitrogen*, 424 F.3d at 1381.
[46] *Egbert,* 104 U.S. at 335.
[46] *Invitrogen,* 424 F.3d at 1381-82.
[47] 471 F.3d 1369 81 USPQ2d 1324 (Fed. Cir. 2006) (73 PTCJ 228, 1/5/07).
[48] *Id.* at 1381.
[49] *Id.*

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were not directed expressly or inherently to a claimed aspect of the invention.[50]

In 2008, the Federal Circuit affirmed another trial court finding of no public use in *In re Omeprazole Patent Litigation*,[51] this time in a decision written by Bryson and joined by Gajarsa and Judge Alan D. Lourie. The court did not reach the lower court's finding that the trials at issue (a series of Phase III trials directed generally to the safety and efficacy of the claimed formulation in various populations) were sufficiently confidential and controlled so that they should not be considered a ''public use.''[52]

Instead, the Federal Circuit in *In re Omeprazole* affirmed the lower court's finding of no public use on the basis that the trials at issue were necessary to show that the claimed invention had been reduced to practice (which the court equated with working for its intended purpose), and so the invention was not ready for patenting.[53] These trials related only generally to the intended, but largely unclaimed, purposes of the invention, which was the long-term stability of the formulation and its efficacy in releasing active ingredient in the upper intestine rather than the stomach of patients.[54]

In *Omeprazole*, the Federal Circuit expressly disagreed with the district court's alternative finding that the experimental use exception prevented a finding of invalidating public use, because the district court's finding was not limited to the time before the invention had been reduced to practice.[55] The Federal Circuit cited several of its own prior cases for the proposition that experimental use cannot negate a public use after the invention has been reduced to practice.[56]

The court did note, however, that this rule has been questioned as inconsistent with the Supreme Court's *Pfaff* decision in Judge Sharon Prost's concurring opinion in *Atlanta Attachment Co. v. Leggett & Pratt Inc.*[57]

In *Atlanta Attachment*, Prost, joined by Judge Timothy B. Dyk, argued that the Supreme Court's discussion of the experimental use exception in *Pfaff* suggested that the experimental use exception could apply beyond reduction to practice of the claimed invention, to permit continued experimentation on claimed features of an invention.[58] Under the Federal Circuit's rule, as applied in *In re Omeprazole*, the experimental use exception can only apply in the time between when the invention is ready for patenting and when it is reduced to practice. In her concurring opinion, Prost argued this result did not make sense and was inconsistent with *Pfaff*.[59]

Pfaff did not address the limits of the experimental use exception, as that issue had not been raised in the case. *Pfaff* focused on distinguishing between commercial and experimental use of a claimed invention, holding that the on-sale bar should apply as soon as an invention is ready for patenting and the subject of a commercial offer for sale.[60] In discussing the experimental use exception, *Pfaff* stated that ''an inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention,'' suggesting that experimental testing may continue beyond the point that the invention is ready for patenting.[61]

Contrasting District Court Decisions

In *Bayer Schering Pharma AG v. Barr Laboratories Inc.*,[62] the principles of *Janssen*, *Eli Lilly*, and *In re Omeprazole* were applied by a district court to find no invalidating ''public use'' arising from several large-scale U.S. Phase III clinical trials.[63] The court found the trials not to be ''public'' because of the study controls and confidentiality restrictions agreed to by doctors participating in the study, even though patients were not subject to any confidentiality restrictions. The court also relied on the fact that the patients did not know the details relating to micronization of the formulation, the subject of the claimed invention.[64]

Bayer also found the trials not to be public because the experimental use exception applied, as the Phase III study on U.S. patients was a necessary part of the reduction to practice of the invention. The court rejected the defendants' argument that previous European Phase III studies involving the formulation were sufficient for the inventors to know that the invention would work for its intended purpose, because the European studies were still being evaluated during the corresponding U.S. studies, and the U.S. patient population was different than the European population and so might have a different safety and efficacy profile.[65]

Interestingly, Bayer had submitted a declaration during prosecution of the patent at issue, informing the examiner of the U.S. trials and explaining how they were part of reduction to practice.[66]

Bayer was not reviewed on appeal, as the patents at issue were found invalid on other grounds (obviousness) and the Federal Circuit affirmed on that basis.[67]

In contrast, *Dey Inc. v. Sepracor Inc.*, [68] recently concluded that a clinical trial conducted by a party other than the patentee (in this case the alleged infringer) was an invalidating public use. Dey, a subsidiary of Mylan Inc., owns patents directed to stable, storable formulations of formoterol (a treatment for chronic obstructive pulmonary disease (COPD)), and sued defendant Sepracor (now Sunovion Pharmaceuticals Inc.) after it launched a formoterol formulation called Brovana.[69]

The asserted public use in *Dey* was a Phase II blinded trial (versus a placebo and other active drugs) conducted by Sunovion, in which some patients received and self-administered a Sunovion formulation that admittedly met all of the claim limitations before the criti-

[50] *SmithKline Beecham*, 365 F.3d at 1317-20.
[51] 536 F.3d 1361, 87 USPQ2d 1865 (Fed. Cir. 2008) (76 PTCJ 623, 8/29/08).
[52] *In re Omeprazole Patent Litigation*, 490 F. Supp. 2d 381, 507-09 (S.D.N.Y. 2006).
[53] *In re Omeprazole*, 536 F.3d at 1372-74.
[54] *Id.* at 1365-66, 1372-74.
[55] *Id.* at 1372.
[56] *Id.*
[57] 516 F.3d 1361, 87 USPQ2d 1865 (Fed. Cir. 2008) (76 PTCJ 623, 8/29/08). *In re Omeprazole*, 536 F.3d at 1372.
[58] *Atlanta Attachment*, 516 F.3d at 1368-70.
[59] *Id.*
[60] *Id.*; *Pfaff*, 525 U.S. at 64-68.
[61] *Id.*
[62] 2008 BL 43010 (D.N.J. March 3, 2008).
[63] *Id.* at *44.
[64] *Id.* at *40-44.
[65] *Id.* at *44-46.
[66] *Id.* at *13.
[67] *Bayer Schering Pharma AG v. Barr Laboratories Inc.*, 575 F.3d 1341 (Fed. Cir. 2009).
[68] 847 F. Supp. 2d 541 (S.D.N.Y. 2012).
[69] *Id.* at 546-47.

cal date. The trials were not completed before the critical date, although some patients finished their assigned doses before the critical date.

The patients self-administered the drug at home and were instructed to use the study medication they were given as directed. Some patients failed to return all of their unused doses. The patients were not told all the components of the formulation required by the claims, although they were told it was a formoterol formulation of a certain strength. Patients were told they may wish to discuss participation in the study with their doctors. Sunovion had its own patent applications on file directed to the tested formulation at time of the study.[70]

Dey held on summary judgment that the Sunovion trial was an invalidating public use. The court relied on the lack of any confidentiality obligation on the part of the physicians or the patients in the study to Dey, the owner of the asserted patents, as well as lack of express confidentiality obligations on part of patients or their physicians to Sunovion.[71]

The court noted that the participants could speak about the trial with their doctors and others, and were ''not prevented'' from using the study medication as they saw fit.[72] The court also pointed out that participants in the trials had lost medicine, yet were given more doses at their next visit. The court concluded that because Sunovion was not trying to hide its use of its formoterol formulation in the trials that its use should be considered a public use.[73]

Dey distinguished other cases finding clinical trials are not public uses (including the *In re Omeprazole*, *Janssen*, and *Bayer v. Barr* decisions) primarily on the basis that the potentially invalidating trial was conducted by the patentee in those cases.[74] The court also concluded that any trial conducted by a third party (any party other than the patentee) could not be considered an experimental use, even though the experimental use exception was expressly not at issue in *Dey*. Based on the facts discussed above, the court concluded the trial was a public use because it found that the invention ''was made accessible to and used by members of the pubic, with no obligation to Dey or enforceable restriction on that use, before the critical date.''[75]

Dey has appealed the district court's summary judgment, arguing that the court erred in concluding that there was no material dispute of fact as to whether Sunovion's clinical trial was sufficiently accessible to the public to constitute an invalidating public use.[76] Dey also argues that the court erred in treating a third party trial differently than one conducted by the patentee for purposes of determining whether it was a public use.[77] It will be interesting to see how the Federal Circuit addresses this case on appeal.

Key Issues Considered by the Courts

From these cases, a brief list of key questions to focus on in any litigation or prosecution raising a clinical trial-related public use issue emerges:

1. ***When was the invention reduced to practice/ready for patenting?*** If the trials were part of determining whether the invention worked for its intended purpose, the trials should not be considered invalidating, because current law requires that the invention be ready for patenting before it can be considered in public use.

2. ***Were all of the claimed aspects of the invention disclosed to participating physicians and patients?*** If not, the Federal Circuit cases support an argument that the invention was not sufficiently accessible to the public to find it in public use.

3. ***Was distribution and use of study medication and information effectively controlled and monitored?*** The Federal Circuit cases suggest that reasonable steps to control distribution and use of medication and information support a finding that the use was not public. The question of the extent of actual control necessary over patients in a third party study is at issue in *Dey*.

4. ***Can the experimental use exception apply to excuse a clinical trial that did disclose the invention to the public in an unrestricted matter?*** In order for the experimental use exception to apply, the trial must be unambiguously experimental (e.g., include data collection and post-study review of results), and have no significant direct commercial purpose. The experimental use exception is more difficult to establish if the trial was conducted after the invention was reduced to practice, because current Federal Circuit law holds that the experimental use exception only applies before reduction to practice. There appears to be room to argue that issue, in good faith, based on Prost's concurring opinion in *Atlanta Attachment*.

AIA Changes Will Make Clinical Trials More Likely to Be Prior Art

The scope of prior art under the AIA has been fundamentally redefined, in several ways that are important in considering when clinical trials may be prior art. New Section 102(a)(1), which will apply to all patents and patent applications having an effective filing date on or after March 16, 2013, states:

> § 102. Conditions for patentability; novelty
>
> (a) Novelty; Prior Art.—A person shall be entitled to a patent unless—
>
> (1) the claimed invention was patented, described in a printed publication, or *in public use*, on sale or *otherwise available to the public* before the effective filing date of the claimed invention;

One key change is the removal of any geographical restriction on public uses as prior art. No longer will uses outside the United States be irrelevant; under the AIA, a public use anywhere in the world can be considered prior art.

Given the worldwide scope of pharmaceutical development efforts, this is potentially a very important change with major ramifications for prosecution disclosure obligations as well as clearance and litigation-related searches.

In addition, the one-year grace period for public uses and sales has been eliminated for all third-party uses and sales; only disclosures by the applicant or with his permission can be excused within the one-year period before filing. This change will make third-party activities such as clinical trials more important as a potential source of prior art.

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[70] *Id.* at 547-49, 551.
[71] *Id.* at 551-52.
[72] *Id.* at 552.
[73] *Id.*
[74] *Id.* at 552-53.
[75] *Id.* at 553.
[76] Brief of Plaintiff-Appellants, *Dey Inc. v. Sepracor Inc.*, No. 2012-1428 (Fed. Cir. July 30, 2012), ECF No. 18
[77] *Id.*

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Even when an applicant makes a disclosure within the one-year period preceding a patent application, the applicant's disclosure may not completely eliminate a third party use as prior art if the applicant's disclosure is not identical.[78]

Further complicating these changes is the increased public availability and access to planned and ongoing clinical trials. Many clinical trials are required to be registered at ClinicalTrials.gov, including all those beyond Phase I with a U.S. site which involve an U.S. Food and Drug Administration-regulated drug product or medical device.[79]

Generally, trials should be registered within 21 days of first patient enrollment, and results should be reported as they are received, or shortly after the drug or device in question is approved by the FDA. [80] Depending on what information is available online, and what information is available from researchers and sponsoring institutions upon request, ClinicalTrials.gov may be considered to function as a sort of index to clinical trials that may facilitate their public availability, like a library index of its holdings facilitates public access to those holdings.

Today, information regarding the protocol and purpose of a clinical trial is generally only available when the results of the trial are published or discovered later in litigation.

What Does 'Available to the Public' Mean in the AIA?

One key construction question raised by the AIA is whether the concluding phrase ''otherwise available to the public'' is intended to create a new, broader category of prior art (such as website postings not meeting the publication requirements), or whether it is intended to operate as a limiting ''public availability'' condition on the well-known, pre-AIA types of prior art listed in Section 102(a)(1)?

There are good reasons to think that both effects are intended, as a matter of plain meaning and based on the legislative history. Based on the plain meaning of the word ''otherwise'' in the context of Section 102(a)(1), a strong argument can be made that all of the items listed in Section 102(a)(1) must be shown to be ''available to the public'' before they can be considered prior art.

And the final committee report issued June 1, 2011, before the Senate passed the House-approved AIA, states in several places that one intent of the term ''otherwise available to the public'' is to emphasize the fact that the art must be publicly accessible.[81] The report also cites statements by the sponsors of the bill that the intent of this language was to abrogate any law (such as the Supreme Court's *Egbert v. Lippman* corset decision) which made a private, uncataloged use, or a secret process, prior art.[82]

The final committee report also notes that the ''public availability'' language was intended to require the same level of public accessibility required by Federal Circuit law. Sen. Jon L. Kyl (R-Ariz.), a sponsor, described this standard as the same as that applied to public accessibility of a publication:

> ''[A]vailable to the public'' means the same thing that ''publicly accessible'' does in the context of a publication. Subject matter makes an invention publicly accessible or available if an interested person who is skilled in the field could, through reasonable diligence, find the subject matter and understand the invention from it.''[83]

Whether this understanding of the scope of the new ''otherwise available to the public'' clause is implemented by the courts remains to be seen. The Patent and Trademark Office has asked for public comment on this question in its proposed regulations seeking to implement new Section 102(a)(1).[84]

Conclusion

The question of when a clinical trial is sufficiently publicly available or accessible to qualify as an invalidating public use continues to be hotly debated in the courts. Current Federal Circuit law strongly suggests that a well conducted clinical trial sponsored by the patentee, with good controls on patients and their use of trial medicine, stands a very good chance of not being considered an invalidating public use, particularly if all of the details regarding the claimed formulation used in the trial are not shared with the doctors and patients in the trial, and the trial was conducted as part of reducing the claimed invention to practice.

This result is being tested in the pending *Dey v. Sepracor* appeal, which applies public use law in the context of a clinical trial that was not conducted by the patentee. While this context is unusual today, it will become more common with the changes implemented by the AIA, and so merits close study.

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[78] 35 U.S.C. § 102(a)(1) (as amended by the Leahy-Smith America Invents Act of 2011, Pub. L. No. 112-29, 125 Stat. 284 (2011)); *Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act*, 77 Fed. Reg. 43,759 (July 22, 2012) (seeking public input) (84 PTCJ 505, 7/27/12).

[79] http://www.clinicaltrials.gov/beta/manage-recs/fdaaa (accessed on Sept. 17, 2012).

[80] *Id.*

[81] H.R. Rep. No. 112-98, at 42-43.

[82] Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 466-475 (2012).

[83] 157 Cong. Rec. S1042 (daily ed. Mar. 1, 2011).

[84] *Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act*, 77 Fed. Reg. 43,759 (July 22, 2012) (84 PTCJ 505, 7/27/12).